

25 (dependent on claim 1 via claim 15) is best presented in independent form, reciting the text of claim 1. Applicants agree to do this as soon as the Examiner indicates whether both Group I and Group II can remain within claim 1.

In regard of the provisional obviousness-type double patenting rejection presented by the Examiner, a Terminal Disclaimer may or may not be appropriate. As prosecution of the parent 09/618,029 application hopefully proceeds to allowance, this issue can be evaluated.

In regard of the section 112 (first paragraph) rejection, binding data is provided (see below) which Applicants believe to be sufficiently responsive to the rejection. However, Applicants also wish to traverse the rejection. In view of the as-filed Specification, it is believed that the claims fully satisfy the requirements of 35 USC section 112, first paragraph.

The as-filed Specification is a full 54 pages long. In introductory sections (pages 1-3, 14-16), it provides a detailed explanation of the involvement (including mechanisms) of somatostatin in various metabolic processes, including participation by various somatostatin receptor subtypes. The compounds of the invention are described in detail (pages 3-8), including listing of numerous species, with concise definitions of terms (pages 11-14). Detailed description of preferred isomers and other preferred structures is also provided (pages 17-20). How the compounds should be formulated as pharmaceuticals (for all the various applications) is described on pages 20-26, along with appropriate dosing, thereby placing the invention well within the possession of those skilled in the art. Synthesis of the compounds of the invention is fully described both by way of reaction schemes and synthesis of representative compounds (pages 26-36). Finally, biological methodology, including assays for agonist and antagonist activity, is described in detail (pages 36-54). Simply stated, the present invention is well enabled. Applicants note that the Office did not choose to make a section 101 rejection, but it is believed that those skilled in the art could hardly find practical utility lacking for the present development.

Applicants believe that the Examiner's citation of various journal articles is misplaced. It does not matter if minor changes in structure lead to dramatic changes in efficacy. It is well established that an Applicant is permitted to claim its invention such that there are included potent species, feeble species, and even species that have no activity at all. There never has been a requirement of US Patent law that even the majority of species in a genus be highly operable, as long as reasonable guidance is provided as to the making of operable species - with disclosure

of the best mode. In this regard, attention is respectfully directed to *Atlas Powder v. E.I. du Pont and Co.*, 750 F.2d 1569, 224 USPQ 409.

With respect to the *Hocart* reference cited by the Examiner, it is again believed that this citation is inappropriate. The *Hocart* compounds are only remotely related to the compounds of the present invention, such that an art rejection was not based thereon. As such, there is not much about the properties of those compounds that can be used to predict the properties of the compounds of the present invention. Similarly, all of the other references cited by the Examiner pertain to different sets of compounds that interact with completely different receptors. All the references are, therefore, irrelevant per se, as a matter of law.

Although Applicants object to the rejections as actually phrased in the Official Action, it is recognized that the examination process is certainly facilitated by making data available. It is hoped that the following will be considered sufficient. Applicants submit herewith a copy of a very recent publication of the inventors herein, Bruce A. Hay et al., "Small Molecule Somatostatin Receptor Subtype-2 Antagonists", *Bioorganic & Medicinal Chemistry Letters*, 11, pp. 2731-2734, 2001. Binding data ( $IC_{50}$ ) for half maximal inhibition of the sst2 receptor is provided in Table 2, page 2733. Data is provided for compounds 1, 2, 5 and 6 (as depicted on page 2732) and also for compounds 7(a-e) (as depicted on pages 2732-2733). It is immediately apparent that binding affinities are well within the range (the low nanomolar range) recognized in the art as demonstrating appropriate pharmacological activity. The fact that compound 1 performed much less well than other compounds does not, as aforementioned, prevent it from being readily included in the generic description of Applicants' invention.

Applicants respectfully disagree with the Examiner concerning the scope of pharmaceutical composition or method of treatment claims that are immediately allowable from the present case, and Applicants believe that all of their claims are allowable as filed. To the extent that any such claims or subject matter are being canceled herewith, Applicants are reserving the right to file one or more continuation or divisional applications directed thereto. It is believed that the remaining pharmaceutical composition claims, as amended, generally obviate the need to further discuss these rejections in this application.

Conclusion

It appears that the remaining issues are best resolved by discussion. Accordingly, the Examiner is respectfully requested to contact the undersigned when convenient. A Petition for Extension of Time (three months) is provided in duplicate, including authorization to charge any needed fee or fee amount to Applicants' Deposit Account, No. 16-1445. An early and favorable action is respectfully requested.

Respectfully submitted,

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